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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,183	07/08/2003	Erin Jessica Lindsay	033528-001	7109

7590 10/11/2007
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Alexandria, VA 22313-1404

EXAMINER

LANG, AMY T

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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10/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/614,183

Applicant(s)

LINDSAY, ERIN JESSICA

Examiner

Amy T. Lang

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 6/26/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/614183 has been reviewed and is NOT accepted.

An attorney registration was not provided on the terminal disclaimer.

Claim Objections

2. **Claim 6** is objected to because of the following informalities: Claim 6, which is dependent from claim 1, recites wherein the "manipulator fork comprises a fork arm and a distal fork." However, claim 1 teaches wherein the manipulator fork is disposed on the distal end of the fork arm. Therefore it is unclear as to how the manipulator fork can be disposed on the fork arm and comprise the fork arm. Furthermore, if applicant were to amend claim 6 to properly recite wherein the manipulator fork is distal of the fork arm; this claim fails to further limit claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

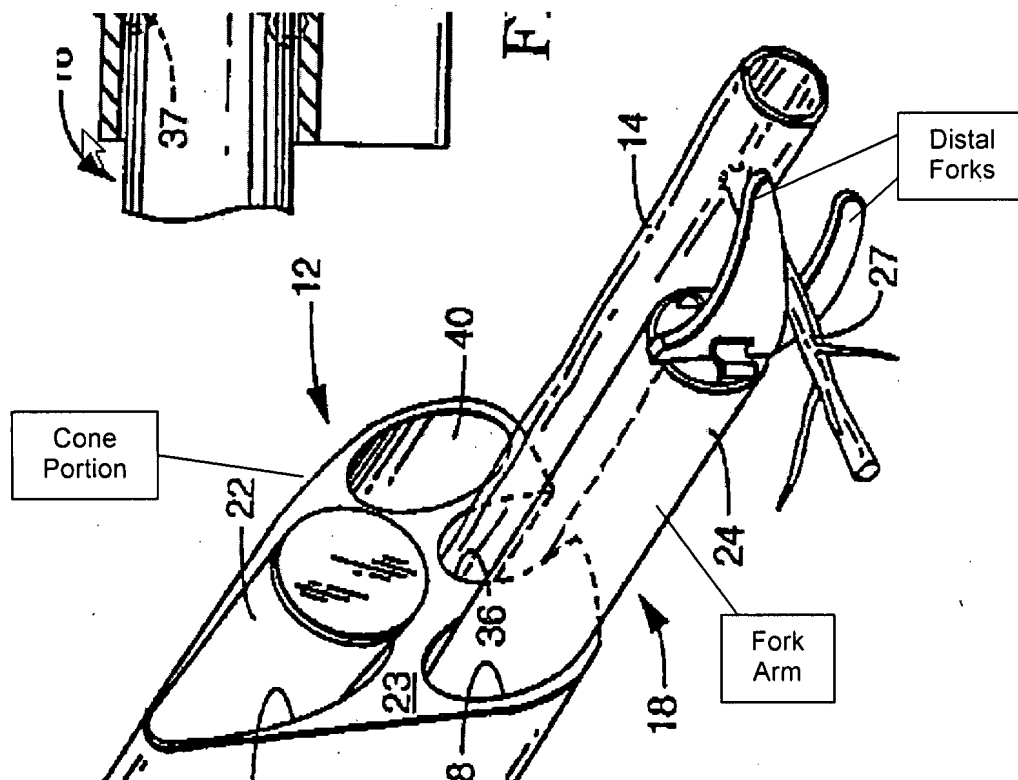
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3731

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. **Claims 1, 3-6, and 11-14** are rejected under 35 U.S.C. 102(b) as being anticipated by Ginn (US 6,022,313).

With regard to **claims 1, 4, 6, and 11-14**, Ginn discloses a surgical device (see entire document) comprising an endoscopic barrel (20) comprising a shaft, a handle at the proximal portion of the shaft, and a conical distal tip (Figure 1; column 3, lines 20-21). As shown in Figures 1 and 2, the shaft comprises multiple lumens, one specific lumen (35) is designed for an endoscope (16) (column 3, lines 47-51; column 4, lines 11-13). Lumen (38) is designed for a manipulator (18) having a fork arm and two distal forks as shown below. The fork arm is extended through the cone portion when dissecting blood vessel (14).



The manipulator and endoscope are received within the shaft when in a retracted position. Therefore, the conical profile of the distal cone is maintained in a retracted position.

As shown in Figures 1 and 2, only viewing lens (22) extends beyond the conical tip and is attached distally to endoscope (16) (column 3, lines 34-37). Therefore, the endoscope remains disposed within the cone portion during harvesting of a blood vessel.

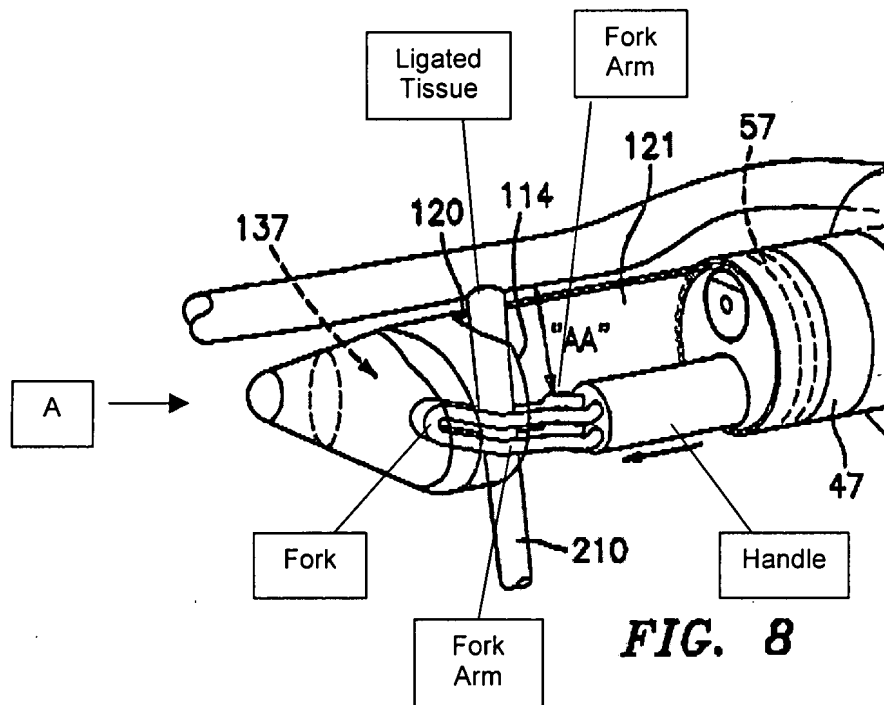
With regard to **claim 3**, as shown in Figure 2, Ginn discloses three lumens (35, 38, and 40) within endoscopic barrel (20). Cutting device (18) extends from the cone portion and ligates a desired blood vessel (14) (Figure 2).

With regard to **claim 5**, manipulator (18) comprises actuator (30), as shown in Figure 1. Since the actuator is directly attached to the distal end of the manipulator, moving the actuator rotationally or translationally will also cause the same movement of the distal fork.

5. **Claims 1, 3-6, and 11-14** are rejected under 35 U.S.C. 102(e) as being anticipated by Bayer (US 2004/0204725 A1).

With regard to **claims 1, 6, and 12**, Bayer discloses a surgical device (see entire document) comprising a shaft, handle, and conical distal tip (Figure 1A). The shaft comprises a plurality of lumens, one specifically for receiving an endoscope ([0018], [0023]). Another lumen receives a ligating/cutting instrument (132) comprising manipulator (134a, 134b), which clearly overlaps a dissecting instrument ([0072], [0073], Figure 3). The manipulator is initially disposed within the distal cone tip (100) when the device is in a retracted position so that the conical profile of the cone is maintained (Figure 1A). When the surgical device is ready to ligate tissue, the cone is advanced away from the manipulator (Figure 3). As shown in Figure 8, the manipulator is extended through the cone portion while dissecting the blood vessel (200). Therefore, the cone provides a recess for receiving the manipulator.

As shown below, the manipulator comprises a handle and two fork arms, each attached to a fork disposed on the distal end. When ligating tissue, each fork arm is extended through the cone portion. Additionally, the cone portion is disposed over the endoscope when the manipulator ligates tissue, as shown in view point A below.



With regard to **claims 3, 4, 11, 13, and 14**, Bayer specifically discloses the shaft comprising an additional lumen receiving a surgical instrument ([0094]).

With regard to **claim 5**, Bayer discloses toggle members (31a and 31b) that controls translational and rotational movement of the shaft (12) and tip (100) ([0077]). Therefore, since the ligating/cutting manipulator (132) is disposed in the conical tip (100), each fork is intrinsically controlled by the toggle members.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 5-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginn (US 6,022,313) or Bayer (US 2004/0204725 A1) in view of Haber (US 5,282,806).

Both Ginn and Haber disclose the invention substantially as claimed. However, neither Ginn nor Haber discloses a rotatable control mechanism slideable with a predefined track on the handle.

Bayer discloses the rotatable control assembly disposed on a track on the handle, used for actuating rotational and translational movement of the tip and shaft of the instrument (paragraph 0077). Ginn and Haber both disclose an endoscopic instrument with a manipulator fork comprising a distal fork and a fork arm. The handles on both instruments actuate rotational movement, or swiveling, of the fork, as well as movement of the distal jaws of the manipulator (col. 4, lines 37-65). The swivel control tube (8) of Bayer causes the manipulator to rotate when the handles are engaged.

Bayer discloses the use of various endoscopic instruments with his device, such as the

instrument of Ginn and Haber. Therefore, it would have been obvious to one of ordinary skill in the art to use the instrument of Ginn or Haber in the device of Bayer.

Response to Arguments

Applicant's arguments filed 6/26/2007 have been fully considered but they are not persuasive.

9. Specifically, applicant argues (A) the amendment filed 1/8/2007 did not amend any claims and therefore could not have necessitated new grounds of rejection. Therefore, the finality of the office action mailed 3/26/2007 should be withdrawn.

With respect to argument (A), the Final Rejection mailed 10/17/2006 has been withdrawn from prosecution in light of applicant's remarks filed 1/8/2007. The Final Rejection mailed 3/26/2007 therefore replaces the Final Rejection mailed 10/17/2006 and refers to amended claims filed 9/28/2007. Therefore the finality of the Final Rejection mailed 3/26/2007 is not withdrawn.

10. Specifically, applicant argues (B) that Bayer does not disclose at least one fork recess in the distal exterior surface of the cone portion for receiving the manipulator fork.

With respect to argument (B), as shown in Figures 5 and 8, Bayer discloses a distal recess on the exterior surface of the cone portion through which the manipulator forks extends.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Lang whose telephone number is (571) 272-9057. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-277-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 3731

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

10/5/2007

Amy T. Lang

ATL


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

10/6/07.